K113265

MAR 2 2 2012

Genii, Inc.
Traditional 510(k) Premarket Submission
gi 4000 Electrosurgical Generator

Section 005 – 510(k) Summary

Submission Correspondent:

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Submission Sponsor:

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Date Prepared: 2 November 2011; Revised 23 February 2012; Revised 14 March 2012

Trade Name: Genii *gi 4000* Electrosurgical Generator

Regulation Number: 878.4400

Classification Name: Electrosurgical cutting and coagulation device and accessories.

Product Code: GEI

Classification Panel: General and Plastic Surgery

Regulatory Class: Class II

Device Description:
The *gi 4000* has seven monopolar outputs, a monopolar argon assisted coagulation output, and a bipolar output. Users make selections from a touch screen that displays stored default power setting start points, convenience and safety information, as well as indications as to current selection mode and return electrode monitoring status.

The *gi 4000* has an integrated peristaltic lavage pump designed to provide lavage washing in the gut, either by accessories connected directly to endoscopes which have dedicated washing channels, or by accessories which introduce lavage fluid into the biopsy port of an endoscope or via dedicated washing channels incorporated into a therapeutic accessory such as a bipolar

endostasis probe. The system is operated by a dual pedal footswitch which controls the lavage pump and power delivery.

The argon output is designed for an argon assisted coagulation method. This method uses 99.999% pure argon gas to provide ionized RF arcs to the targeted tissue. The monopolar outputs are designed for cutting and coagulation methods. The unit is designed with a standard monopolar active cord receptacle (foot switch activated).

Endoscopic accessories connect to the monopolar receptacle via a widely available detachable active cord accessory. Both the monopolar and argon outputs require the use of a patient return electrode (grounding pad) to return the RF energy from the patient back to the generator. The unit is designed with a standard GI bipolar single jack receptacle. No patient return electrode (grounding pad) is needed for bipolar methods. The output power of the argon, monopolar and bipolar methods are independently controlled through a touch panel LCD display located on the front panel of the generator.

The argon gas for the argon output is exclusively supplied by the disposable Genii Argon Gas Canister. Each canister contains 49 liters of ultra-high purity (99.999% pure) argon gas (certified). When using the Argon Coagulation Method, the ArConnect is intended for single-use only and will be supplied as a non-sterile, disposable item. The ArConnect has been designed to allow the delivery of monopolar high frequency electrosurgical energy and argon gas to a single use argon coagulation probe sold separately. The ArConnect is supplied individually packaged in disposable packaging and is not to be reprocessed or re-used.

Indications for Use:
The *gi 4000* Electrosurgery Generator is intended to deliver electrosurgical outputs to perform cutting and/or coagulation and coagulation with or without delivery of argon gas in flexible endoscopic applications. The integrated lavage pump is intended to wash tissue or mucosa within the gut when used in conjunction with washing catheters or bipolar endoscopic probes, endoscope water jet channels, or endoscope working channels. The Genii ArConnect™ Conducting Adapter is intended for use with the *gi 4000* during argon assisted coagulation.

Predicate Devices:

1. Olympus AFU-100 Peristaltic Pump Unit (PPU); K073207
2. Erbe APC 300 Argon Plasma Coagulator and Accessories; K963189
3. Erbe ICC 200 Electrosurgical Workstation for Flexible Endoscopy; K933157
4. Erbe APC Connector Hose and Probes; K013348

Summary of Technical Comparisons:
The following table compares ***gi 4000*** Electrosurgery Generator to the predicate devices with respect to intended use, target population, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

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gi 4000 Electrosurgical Generator

Manufacturer	**Genii**	**Olympus**		
Trade Name	***Gi 4000***	**Olympus AFU-100**	**Erbe APC 300**	**Erbe ICC 200**
510(k) Number	NA	K073207	K963189	K933157
Product Code	GEI	FEQ (with GEI)	GEI	GEI
Regulation Number	878.4400	876.1500 (with 878.4400)	878.4400	878.4400
Regulation Name	Electrosurgical cutting and coagulation device and accessories	Pump, air non manual, for endoscope (with Electrosurgical cutting and coagulation device and accessories)	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Intended Use	The gi 4000 Electrosurgery Generator is intended to deliver electrosurgical outputs to perform cutting and/or coagulation and coagulation with or without delivery of argon gas in flexible endoscopic applications. The integrated lavage pump is intended to wash tissue or mucosa within the gut when used in conjunction with washing catheters or bipolar endoscopic probes, endoscope water jet channels, or endoscope working channels.	The Olympus AFU-100 peristaltic flushing pump is intended for irrigation of instruments or irrigation/flushing/ cleansing of tissue surfaces and wounds supporting endoscopic diagnosis or therapy.	The Erbe APC 300 Argon Plasma Coagulator is an argon gas delivery system that is designed for coagulation when used in combination with Erbe ICC electrosurgery Generators and Erbe APC Probes.	The ICC 200 is intended to deliver high frequency electrical current for the cutting/or coagulation of tissue.
Pump Type	Peristaltic	Peristaltic	n/a	n/a
Flow Rate	0-735 ml/minute(tubing dependent)200 ml max through leur valves	0-600ml/minute (tubing dependent) 200 ml max through leur valves	n/a	n/a
Dimensions (Width x Height x Depth)	16" x 6.5" x 16" (19.5 X 7 X 19 max overall including pump head, water bottle holder and feet)	295 X 430 X115 mm (note millimeters not inches)	APC 16" x 4" x 14.5" (needs cart for gas tanks)	11" x 6" x 14.5"
Max Voltage Peak	4200 Vp.	n/a	n/a	4000 Vp
Frequency	315-550 KHz.	n/a	n/a	330-1,000 KHz (1 MHz).
Output Power Limit	60-200 watts.	n/a	n/a	120-200 watts
Gas Flow Rate	0.1-2.0 mL/minute.	n/a	0.1-9.0 mL/minute.	n/a
Gas Purity	99.999%.	n/a	99.998%.	n/a
Tank Size	49 liters.	n/a	2 X 934 liters.	n/a
Electrical Safety/other standards	IEC 60601-1 IEC 60601-1-2, IEC 60601-2-2, CISPR 11, IEC 62304, ISO 14971	IEC 60601-1, UL 60601-1, IEC 60601-1-2, IEC 60601-1-4	ANSI/AAMI HF-18/1993, IEC 60601-1-2	Not known
Wave Form •Mono Soft Coag •Mono Coag •Mono Blend Cut	 Continuous Sine Modulated Alternating 50%DC	n/a	n/a	 Continuous Sine Modulated n/a

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gi 4000 Electrosurgical Generator

Manufacturer	**Genii**	**Olympus**		
Trade Name	***Gi 4000***	**Olympus AFU-100**	**Erbe APC 300**	**Erbe ICC 200**
•Mono Cut	Continuous sine			Continuous sine
•Bipolar	Continuous sine			Continuous sine
•Argon	Modulated			Modulated
Max Voltage Peak		n/a	n/a	
•Mono Soft Coag	300			190
•Mono Coag	2200			2300-2500
•Mono Blend Cut /PBC	1625/1050			n/a (EC)
•Mono Pulse Cut	1000			380-600/190 (EC)
•Mono Cut	780			600
•Bipolar	104			190
•Argon	4200			4000
Frequency (KHz)		n/a	n/a	
•Mono Soft Coag	350KHz			330KHz
•Mono Coag	460-500KHz			1,000KHz
•Mono Blend Cut/PBC	350/350			n/a
•Mono Pulse Cut	350			330
•Mono Cut	350			330
•Bipolar	350			350
•Argon	460-500			1,000KHz
Max Power				
•Mono Soft Coag	120 Watts @ 100 Ω	n/a	n/a	120 Watts @ 125 Ω
•Mono Coag	120 Watts @ 500 Ω			120 Watts @ 350 Ω
•Mono Blend Cut/ PBC	120 Watts @ 500 Ω/ 120 Watts @ 500 Ω			n/a
•Mono Pulse Cut	120 Watts @ 500 Ω			200 Watts @ 500 Ω
•Mono Cut	200 Watts @ 500 Ω			200 Watts @ 500 Ω
•Bipolar	60 Watts @ 400 Ω			120 Watts @ 125 Ω
•Argon	120 Watts @ 500 Ω			99 Watts @ 350 Ω
Duty Cycle		n/a	n/a	
•Mono Soft Coag	100%			100%
•Mono Coag	6%			4% - 6%
•Mono Cut	100%			100%
•Bipolar	100%			100%
Crest Factor		n/a	n/a	
•Mono Soft Coag	1.4			1.4
•Mono Cut	1.4			1.4
•Bipolar	1.4			1.4
Power Curve		n/a	n/a	
•Mono Soft Coag	Narrow			Narrow
•Mono Coag	Wide			Wide
•Bipolar	Narrow			Narrow
Pulse Speed		n/a	n/a	
•Mono Pulse Blend Cut	700ms ON/50ms OFF			750ms ON/50ms OFF
•Mono Pulse Cut	700ms ON/50ms OFF			750ms ON/50ms OFF

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The following table compares Genii ArConnect accessory to the predicate accessory device.

Manufacturer	**Genii**	
Trade Name	**Genii ArConnect**	**Erbe APC Connector Hose**
510(k) Number	NA	K013348
Product Code	GEI	GEI
Regulation Number	878.4400	878.4400
Regulation Name	Electrosurgical cutting and coagulation device and accessories	Electrosurgical cutting and coagulation device and accessories
Intended Use	The Genii ArConnect conducting adapter is intended for use with the Genii GI4000 during argon assisted coagulation.	The APC Connector Hose and Probes are intended for use in argon plasma coagulation. The device is used to treat many conditions in endoscopy for various surgical procedures.
Material	PVC tubing Shore A75+3Clear, Cable 24AWG Terminal: brass with nickel and Gold plating; Insert: ABS PA707 with EX-33084 white; Overmold HDPE LH523, nature; PE white, #PEM864; Gas Tube: ABS PA707, with EX-33084 White; O ring: AS 568-008, Katon P/N: OR-NB50NL-008-BK, ShoreA: 50, BUNA-U; Heat shrink sleeve band: 82*98.5*	Polyamide, PEEK, Thermoflex, silicone.
Length	5 feet.	6.5 feet.
Back Flow	Integrated in the generator gas flow design	A separate back flow filter/valve is sold separately to be used with the hose.
How Supplied	Single use; disposable.	Re-useable.

Non-clinical Data – Bench Testing:
As part of demonstrating safety and effectiveness of the Genii *gi 4000* Electrosurgical Generator and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, the following testing has been performed:

In vitro testing
Electrical Safety
EMC
Biocompatibility
Software Testing

In Vitro Testing: An *in vitro* tissue study was conducted to compare the lesions created by the subject *gi 4000* electrosurgical generator and the predicate Erbe ICC 200E with APC 300 system when using equivalent outputs. This *in vitro* study demonstrated substantial similarity between lesions created by the subject *gi 4000* device and the predicate Erbe ICC 200E with APC 300 system. The data demonstrate that the performance of the subject device is equivalent to the predicate devices.

Electrical Safety and EMC: The *gi 4000* Electrosurgical Generator has been tested and met the requirements of the Electrical Safety and EMC standards used.

Biocompatibility Testing: Cytotoxicity, Irritation and Sensitization testing have been completed on the ArConnect Conducting Cable. The test results demonstrate that the ArConnect Conducting Cable is non-toxic.

Software Verification and Validation: Software verification and validation testing has been performed on the *gi 4000* Electrosurgical Generator.

Safety and Effectiveness:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the Genii *gi 4000* Electrosurgical Generator and the predicate devices do not raise any questions regarding its safety and effectiveness. The Genii *gi 4000* Electrosurgical Generator, as designed and manufactured, therefore is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Genii, Incorporated
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Ms. Julie Powell
611 West 5th Street, Third Floor
Austin, Texas 78701

MAR 22 2012

Re: K113265
Trade/Device Name: gi 4000 Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 14, 2012
Received: March 15, 2012

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: *gi 4000* Electrosurgical Generator

Indications for Use:

The *gi 4000* Electrosurgical Generator is intended to deliver electrosurgical outputs to perform cutting and/or coagulation and coagulation with or without delivery of argon gas in flexible endoscopic applications. The integrated lavage pump is intended to wash tissue or mucosa within the gut when used in conjunction with washing catheters or bipolar endoscopic probes, endoscope water jet channels, or endoscope working channels. The Genii ArConnect™ Conducting Adapter is intended for use with the *gi 4000* during argon assisted coagulation.

Prescription Use __X__ (21 CFR Part 801 Subpart D)

And/Or Over the Counter Use_____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Device Evaluation

510(k)_____

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113265